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10/081,119	02/21/2002	Christoph Reinhard	PP-16932.002	8543

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EXAMINER	
VIVLEMORE, TRACY ANN	
ART UNIT	**PAPER NUMBER**
1635	

DATE MAILED: 06/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/081,119	REINHARD ET AL.	
	Examiner	Art Unit	
	Tracy Vivlemore	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-34* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5,7, drawn to a method for reducing growth of a cancerous cell with an agent wherein the agent is a TTK antisense polynucleotide, classified in class 514, subclass 44.

II. Claims 1-2, 5-7, drawn to a method for reducing growth of a cancerous cell with an agent wherein the agent is a monoclonal antibody that specifically binds TTK, classified in class 424, subclass 9.34.

III. Claims 8-15, drawn to an assay for identifying a candidate agent that reduces growth of a cancerous cell, classified in class 424, subclass 387.7.

IV. Claims 16-24, drawn to a method of identifying an agent that reduces TTK activity, classified in class 435, subclass 7.71.

V. Claims 25-27, drawn to a method of detecting cancer other than ovarian by detecting the level of expression of a TTK polypeptide, classified in class 514, subclass 2.

VI. Claims 28-30, drawn to a method of detecting cancer other than ovarian by detecting the level of expression of a TTK polynucleotide, classified in class 514, subclass 44.

VII. Claims 31-34, drawn to a method of assessing the prognosis of a cancerous disease other than ovarian cancer by detecting the level of

expression of a TTK-encoding polynucleotide, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The mode of operation of Invention I is to reduce growth of a cancerous cell using a TTK antisense polynucleotide while the mode of operation of invention II is to reduce growth of a cancerous cell using a monoclonal antibody that specifically binds TTK.

3. Claim 1 link(s) inventions I and II. Claims 2, 5 and 7 are generic to groups I and II. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C.

121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

4. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention I is to reduce growth of a cancerous cell with an agent wherein the agent is a TTK antisense polynucleotide while the function of invention III is to identify a candidate agent that reduces growth of a cancerous cell.

5. Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention I is to reduce growth of a cancerous cell with an agent wherein the agent is a TTK antisense polynucleotide while the function of invention IV is to identify an agent that reduces TTK activity.

6. Inventions I and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Invention I operates by reducing growth of a cancerous cell with an agent wherein the agent is a

TTK antisense polynucleotide while invention V operates to detect cancer other than ovarian by detecting the level of expression of a TTK polypeptide.

7. Inventions I and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Invention I operates to reduce growth of a cancerous cell with an agent wherein the agent is a TTK antisense polynucleotide while invention VI operates to detect cancer other than ovarian by detecting the level of expression of a TTK polynucleotide.

8. Inventions I and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Invention I operates to reduce growth of a cancerous cell with an agent wherein the agent is a TTK antisense polynucleotide while invention VII operates to assess the prognosis of a cancerous disease other than ovarian cancer by detecting the level of expression of a TTK-encoding polynucleotide.

9. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. Invention II functions to reduce growth of a cancerous cell with an agent wherein the agent is a monoclonal

antibody that specifically binds TTK while the function of invention III is to identify a candidate agent that reduces growth of a cancerous cell.

10. Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. Invention II functions to reduce growth of a cancerous cell with an agent wherein the agent is a monoclonal antibody that specifically binds TTK while the function of invention IV is to identify an agent that reduces TTK activity.

11. Inventions II and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Invention II operates to reduce growth of a cancerous cell with an agent wherein the agent is a monoclonal antibody that specifically binds TTK while the function of invention V operates to detect cancer other than ovarian by detecting the level of expression of a TTK polypeptide.

12. Inventions II and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The mode of operation of Invention II is to reduce growth of a cancerous cell with an agent wherein

the agent is a monoclonal antibody that specifically binds TTK while the mode of operation of invention VI functions to detect cancer other than ovarian by detecting the level of expression of a TTK polynucleotide.

13. Inventions II and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of Invention II is to reduce growth of a cancerous cell with an agent wherein the agent is a monoclonal antibody that specifically binds TTK while the function of invention VII is to assess the prognosis of a cancerous disease other than ovarian cancer by detecting the level of expression of a TTK-encoding polynucleotide.

14. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. Invention III operates to identify a candidate agent that reduces growth of a cancerous cell while invention IV operates to identify an agent that reduces TTK activity.

15. Inventions III and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention III is to identify a candidate agent that reduces growth of a cancerous cell

while the function of invention V is to detect cancer other than ovarian by detecting the level of expression of a TTK polypeptide

16. Inventions III and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention III is to identify a candidate agent that reduces growth of a cancerous cell while the function of invention VI is to detect cancer other than ovarian by detecting the level of expression of a TTK polynucleotide.

17. Inventions III and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention III is to identify a candidate agent that reduces growth of a cancerous cell while the function of invention VII is to assess the prognosis of a cancerous disease other than ovarian cancer by detecting the level of expression of a TTK-encoding polynucleotide.

18. Inventions IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention IV is to identify an agent that reduces TTK activity while the function of

invention V is to detect cancer other than ovarian by detecting the level of expression of a TTK polypeptide.

19. Inventions IV and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention IV is to identify an agent that reduces TTK activity while the function of invention VI is to detect cancer other than ovarian by detecting the level of expression of a TTK polynucleotide.

20. Inventions IV and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different functions. The function of invention IV is to identify an agent that reduces TTK activity while the function of invention VII is to assess the prognosis of a cancerous disease other than ovarian cancer by detecting the level of expression of a TTK-encoding polynucleotide.

21. Inventions V and VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The mode of operation of invention V is to detect cancer other than ovarian by detecting the level of

expression of a TTK polypeptide while the mode of operation of invention VI is to detect cancer other than ovarian by detecting the level of expression of a TTK polynucleotide.

22. Inventions V and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The mode of operation of invention V is to detect cancer other than ovarian by detecting the level of expression of a TTK polypeptide while the mode of operation of invention VII is to assess the prognosis of a cancerous disease other than ovarian cancer by detecting the level of expression of a TTK-encoding polynucleotide.

23. Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation. The mode of operation of invention VI is to detect cancer other than ovarian by detecting the level of expression of a TTK polynucleotide while the mode of operation of invention VII is to assess the prognosis of a cancerous disease other than ovarian cancer by detecting the level of expression of a TTK-encoding polynucleotide.

24. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Restriction to a single amino acid sequence

Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the sequences listed in the claims of invention III are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application. (See MPEP 803.04 and 2434)

25. The claims of invention III specifically claim amino acid SEQ ID NOS 14, 26, 27, and 28. Although these sequences are all part of TTK, the sequences are considered to be unrelated since each sequence claimed has a unique amino acid sequence, which represents a separate area of the TTK polypeptide.

26. Furthermore, a search of more than one (1) of the sequences claimed in invention III presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Accordingly, if invention III is elected, applicants must further elect one (1) sequence from SEQ ID NOS 14, 26, 27, and 28.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

27. A telephone call was made to James Keddie on May 19, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John Leguyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

TV
May 26, 2004

KAREN A. LACOURCIERE, PhD
PRIMARY EXAMINER

Tracy Vivlemore
Examiner
Art Unit 1635